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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/786,937	01/22/97	BOUCHARD P	235299/96001

HM12/1024

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EXAMINER	
DELACROIX MUIRHEI,C	
ART UNIT	**PAPER NUMBER**
1614	22

DATE MAILED: 10/24/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
08/786,937	BOUCHARD et al.
Examiner	**Group Art Unit**
Cybille Delacroix-Muirheid	1614

☒ Responsive to communication(s) filed on *July 31, 2000*.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *15, 16, 18-24, and 26-37* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *15, 16, 18-24, and 26-37* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Continued Prosecution Application

1. The request filed on July 31, 2000 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08/786,937 is acceptable and a CPA has been established. An action on the CPA follows.

New claims 34-37 are added. No claims are cancelled.

Claims 15, 16, 18-24 and 26-37 are currently pending.

Claim Objections

2. Claims 15, 21 and 32 are objected to because of the following informalities: in claim 15, line 4, the phrase "improvement of administering" is awkward. The Examiner suggests cancelling "of" and adding --comprising--. This is consistent with US patent practice. In claim 21, lines 1-2, the phrase "in which Cetrorelix is administered either in a.." is awkward. The Examiner would suggest cancelling "in which" and adding --comprising administering-- in line 1. Additionally, "is administered either" should be cancelled and the word --either-- should be added after the first occurrence of "in". Finally, in claim 32, line 2, "are given" should be cancelled and replaced with --is administered--. Appropriate correction is required.

3. Claims 18 and 19 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or

rewrite the claim(s) in independent form. Claims 18 and 19 fail to further limit the method of claim 15 because they do not set forth active method steps which are necessary to further limit method claims.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was

made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 15, 16, 18-24, 26-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diedrich et al. in view of Felberbaum et al.

Diedrich et al. disclose a method of inducing ovarian stimulation in tubal sterile patients by administering a combination of exogenous gonadotrophins (HCG) and the LHRH antagonist Cetrorelix to said patients. Cetrorelix was administered at a dosage 3 mg daily starting on day 7 of the menstrual cycle. Diedrich also disclose that GnRH agonists given in combination with exogenous gonadotropins also results in more effective stimulation. Finally, Diedrich discloses suppression of LH surges while also suggesting that under Cetrorelix treatment, suppression of FSH is less pronounced. Please see page 790, second full paragraph. Please also see the abstract; page 789, **Results**, first full paragraph; page 790, second column, first full paragraph; page 791, first column, third paragraph.

Diedrich does not specifically teach treating infertility, yet the Examiner refers to Felberbaum et al. which teaches treating women with tubal infertility with a combination of exogenous gonadotropins (HMG) and Cetrorelix, wherein the Cetrorelix is administered subcutaneously at 3mg or 1 mg daily starting on day 7 of the menstrual cycle. Kindly refer to the abstract.

It would have been obvious to one of ordinary skill in the art to use the method taught by Diedrich to treat infertility because Felberbaum raises expectation of success by disclosing that ovarian stimulation is induced and further because Felberbaum, in addition to Diedrich, teaches that the disclosed treatment would be effective in the treatment Polycystic Ovary Disease.

Furthermore, both Diedrich and Felberbaum disclose administration of the same gonadotropin/Cetrorelix combination to a patient using the same method steps and dosages set forth in Applicant's claims. Accordingly, treatment of fertility disorders would have been obvious.

With respect to using LH, LHRH or a LHRH agonist to inducing ovulation instead of HCG (taught by art), such a modification would have been obvious to one of ordinary skill in the art because it is known that the overall effect of LH and its agonists are to induce ovulation.

Concerning claims 35 and 37, which recites a dose regimen of .25 mg/day, since Diedrich and Felberbaum have established that the efficacy of Cetrorelix is dependent upon its concentration, it would have been obvious to one of ordinary skill in the art to further modify the method of Diedrich and Felberbaum such that the Cetrorelix is present in a dose regimen that is effective to optimize its effect on ovarian stimulation.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 21, 22 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Diedrich et al.

Diedrich et al. disclose a method of inducing ovarian stimulation in tubal sterile patients by administering a combination of exogenous gonadotrophins (HCG) and the LHRH antagonist

Cetrorelix to said patients. Cetrorelix was administered at a dosage 3 mg daily starting on day 7 of the menstrual cycle. Please see the abstract; page 789, **Results**, first full paragraph; page 790, second column, first full paragraph; page 791, first column, third paragraph.

Claims 22 and 33 are anticipated by Diedrich because Diedrich discloses administration of the same active agent, i.e. Cetrorelix, to a patient using Applicant's claimed method steps. Accordingly, induction of ovulation between day 9 and 20 or 9 and 16 of the menstruation cycle is inherent.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 15, 16, 18-24, 26-37 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 22-25, 30, 31, 33-39, 41-48 of copending Application No. 09/053,152. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant application and '152 claim methods for treating infertility disorders comprising administering, in addition to

exogenous gonadotropins, an effective amount of an LHRH antagonist to suppress endogenous LH while maintaining FSH secretion at a natural level. Determination of the specific commercially known gonadotropins used to stimulate follicle growth is obvious and well within the capability of the skilled artisan.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

11. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See Miller v. Eagle Mfg. Co., 151 U.S. 186 (1894); In re Ockert, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

12. Claims 21, 22 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 34-35 of prior U.S. Patent No. 09/053,152 is a double patenting rejection.

Conclusion

Claims 15, 16, 18-24, 26-37 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cybille Delacroix-Muirheid whose telephone number is (703) 306-3227. The examiner can normally be reached on Tue-Fri from 8:30 to 6:00. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Cintins, can be reached on (703) 308-4725. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

CDM
Oct. 22, 2000

Cybille Delacroix-Muirheid
Patent Examiner Group 1600